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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,877	04/28/2005	Zofre Bayram-Hahn	MERCK-3009	9004
24997 7590 12/05/2008 MILLEN, WHITE, ZELANO & BRANIGAN, PC 2200 CLARENDON BLVD SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
VO, HAI				
ART UNIT		PAPER NUMBER		
1794				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,877

Applicant(s)

BAYRAM-HAHN ET AL.

Examiner

Hai Vo

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/09/2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22-24 is/are pending in the application.
4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5, 12-20 and 22-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

1. All of the art rejections are maintained.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 12-20, and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by "*the pores* are retained after coating". Do Applicants want to convey the pore size or the pore morphology?

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 2, 4, 5, 14, 16, 17, 19, and 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP

838 257. EP '257 discloses a monolithic molding for chromatographic separation made from a porous inorganic body coated with a polymeric material (column 3, lines 10-25). The monolithic molding has multiple through channels which read on the claimed pores. Note that the claim does not require the mesopores having the surfaces coated with a polymer. The polymeric coating is in the form of a tube which fuses to and coats the inner surfaces of the channels (claim 1). Likewise, the through channel of the monolithic molding is in the form of a tube as well and would have one side longer than the other. The solvent is applied to the film and inner surface of the channel (claim 6). The solvent reads on the claimed cladding. EP '257 discloses no deposition of coating in the mesopores and the coating does not penetrate into the inner porosity of the monolithic molding (page 4, column 5, lines 1-10). It is respectfully submitted that the pore size of the coated monolithic molding is retained after coating. The coating is styrene/divinylbenzene, methacrylic acid derivatives that are physically adsorbed on the porous silica shaped body (claim 2). It appears that EP'257 uses the same material forming a coating as Applicants; therefore, it is not seen that the coating could not be stable against NaOH as like material has like property. The molding is columnar and has a diameter of 0.254 cm (example 1). EP'257 does not specifically disclose the processing steps as set forth in the claims, i.e., precipitating step as well as forcing the organic polymer through the molding under pressure and afterward lowering the temperature. However, they are product-by-process limitations not as yet shown to produce a patentably distinct

article. It is the examiner's position that the article of EP'257 is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with EP'257. Accordingly, EP'257 anticipates or strongly suggests the claimed subject matter.

7. Claims 3, 15, and 18 and rejected under 35 U.S.C. 103(a) as being unpatentable over EP 838 257 as applied to claim 1 above, and further in view of WO 98/58253. Cabrera et al (US 6,398,962) will be relied on as an equivalent form of WO 98/58253. EP '257 does not specifically disclose the monolith having macropores and mesopores and its length. Cabrera, however, discloses a

monolithic moulding for chromatographic separation made from a porous shaped SiO_2 body having interconnected macropores and mesopores in the walls of macropores wherein the macropores have an average pore size of greater than 0.1 microns and the mesopores having an average pore size of 2 nm to 100 nm (column 2, lines 20-25). Cabrera '962 discloses that the molding is columnar, having a diameter of 1 cm or greater and a length of 9.3 cm (column 3, lines 20-22, example A1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the porous monolith of Cabrera '962 for the chromatographic separation motivated by the desire to provide high flow rates at a moderate operating pressure, thereby achieving improved productivity.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 838 257 as applied to claim 1 above, and further in view of Dhingra et al (US 6,054,052). EP'257 does not specifically disclose the flat monolithic sorbent and its thickness. Dhingra, however, teaches a porous inorganic sorbent in the form of a flat membrane having a thickness 0.02 to 1000 microns, encompassing the claimed range (column 25, lines 1-8; column 24, lines 5-6). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a porous inorganic monolithic in the form of flat membrane with a thickness as taught by Dhingra because such a thickness is sufficient for the inorganic sorbent in performing the efficiency of the separation.

9. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 838 257 as applied to claim 1 above, and further in view of Li et al (US 7,125,448). EP' 257 does not specifically disclose the monolithic being modified with a copolymer of tetraalkoxysilane and methyltrialoxysilane. Li, however, teaches a silica monolith having surface modified with at least two silanes wherein one silane is an endcapping silane (abstract, column 16, lines 25-35, and table 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the porous silica monolith having surface treated with the silanes as described by Li motivated by the desire to retain polar analytes reproducibly under highly aqueous conditions.
10. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 838 257 as applied to claim 1 above, and further in view of Ohno et al (US 4,483,940). EP '257 does not specifically disclose the coating including polymer (2-hydroxyethyl methacrylate). Ohno, however, teaches a coated monolithic material comprising a silica monolith coated with polymer (2-hydroxyethyl methacrylate) (column 4, lines 10-20). The coating polymer is present in an amount of 0.02% to 10% by weight (column 4, lines 48-53). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use polymer (2-hydroxyethyl methacrylate) as a coating material for the porous silica monolith because it has been shown in the art that polymer (2-hydroxyethyl methacrylate) is a typical form of the polyacrylate that could be widely used as a coating for the silica monolith.

EP'257 does not specifically disclose the carbon content. However, it appears that EP'257 as modified by Ohno uses the same coating material and the same concentration of the coating material as Applicants and the carbon content depends from such a concentration. Therefore, it is not seen that the carbon content could have been outside the claimed range.

11. The art rejections based on EP '257 have been maintained for the following reasons. Applicants contend that EP'257 fails to teach or suggest the surfaces of the pores coated with a polymer. The examiner respectfully disagrees. It is true that EP'257 requires that the polymer does not penetrate into the mesopores. However, nothing in the claim is specific about the surfaces of the mesopores coated with the polymer. EP '257 teaches that the monolithic molding comprises a plurality of through channels. The polymeric coating fuses to and coats the inner surfaces of the through channels (claim 1). The through channels read on the claimed pores having the surfaces coated with the polymer. The coating is styrene/divinylbenzene, methacrylic acid derivatives that are physically adsorbed on the porous silica shaped body (claim 2). It appears that EP'257 uses the same material forming a coating as Applicants; therefore, it is not seen that the coating could not be stable against NaOH as like material has like property. The molding is columnar and has a diameter of 0.254 cm (example 1). EP'257 does not specifically disclose the processing steps as set forth in the claims, i.e., precipitating step as well as forcing the organic polymer through the molding under pressure and afterward lowering the temperature. However, they are

product-by-process limitations not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of EP'257 is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with EP'257.

Other secondary references do not need to address a dense protective layer which is stable against NaOH and provided on the inner pore surfaces of the mouldings because the issues were already taught by EP'257. Accordingly, the art rejections based on EP'257 are sustained.

12. Claims 1, 2, 4, 5, 12, 16-17, 19, and 22-24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stanton et al (US 4,851,163). Stanton discloses a porous ceramic diffuser for waste water treatment made from a porous ceramic body coated with a biocidal material (column 2, lines 30-37). The biocidal is chemically or physically bonded in a shallow layer extending inwardly from the exposed surface of the porous ceramic body (column 2, lines 20-30). The examiner notes with appreciation that shallow layer is not corresponding to the claimed cladding as pointed out by Applicants. The diffuser comprises an upper layer of epoxy which instead reads on the claimed cladding. The porosity of the coated ceramic body is preserved after coating (column 2, lines 29-32). The porous ceramic body is silica, alumina (column 3, lines 20-25). The coating is a polymethacrylate (example 1). It appears that Stanton uses the same material for a coating as Applicants, therefore, it is not seen that the coating could not be stable against NaOH as like material has like property. The porous ceramic diffuser is in the form of a tube, a plate (claim 7, column 3, lines 60-65; column 4, lines 5-10). Stanton does not specifically disclose the carbon content. However, it appears that Stanton uses the same coating material and the same concentration of the coating material as Applicants and the carbon content depends from such a concentration (example 1). Therefore, it is not seen that the carbon content could have been outside the claimed range. Stanton does not specifically disclose the processing steps as set forth in the claims, i.e., precipitating step as well as forcing the organic

polymer through the molding under pressure and afterward lowering the temperature. However, they are product-by-process limitations not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of Stanton is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with Stanton. Accordingly, Stanton anticipates or strongly suggests the claimed subject matter.

13. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanton et al (US 4,851,163) as applied to claim 1 above, and further in view of Johnson (US 2002/0041041). Stanton does not specifically disclose a

porous ceramic diffuser having a length and a diameter set forth in the claims.

Johnson, however, teaches a hollow monolithic ceramic diffuser having a length of from 50 to 762 mm and a width of from 6 to 90 mm (claim 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the porous silica monolith having a dimension as taught by Johnson because such is a typical size of the ceramic diffuser being used in the art.

14. The art rejections over Stanton have been maintained for the following reasons.

Applicants argue that Stanton contemplates the polymer coating grafted to the surfaces of the grains; therefore, Stanton does not teach or suggest the coating penetrating into the inner pores of the ceramic diffuser. The examiner respectfully disagrees. The examiner directs Applicants' attention to column 2, lines 25-30 and column 3, lines 35-45 of Stanton. The biocidal material penetrates into the pores of the ceramic diffuser wherein the pore structure is defined by spaces among the ceramic particles. The examiner notes with appreciation that shallow layer is not corresponding to the claimed cladding as pointed out by Applicants. The diffuser comprises an upper layer of epoxy which instead reads on the claimed cladding. The precipitating step as well as the step of forcing the organic polymer through the molding under pressure and afterward lowering the temperature are related to product-by-process limitations which are not as yet shown to produce a patentably distinct article. The burden has been shifted to the applicant to show unobvious differences between the claimed

product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). Accordingly, the art rejections are sustained.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/
Primary Examiner, Art Unit 1794